PROFESSIONAL INFORMATION

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

TEEJEL (gel)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of gel contains 87,1 mg choline salicylate.

Excipients with known effect:

1 g of this medicinal product contains 38,2 % *m/m* ethanol (alcohol)

For the full list of excipients, see section 6.1.

Teejel is sugar free.

3. PHARMACEUTICAL FORM

Clear, colourless to slightly yellowish, viscous gel with an aniseed-like odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Teejel is used to treat pain and inflammation associated with

- Aphthous ulcers, and other oral ulcerations and abrasions
- Denture sores
- Gingivitis
- Glossitis
- Thrush
- Herpes labialis
- Cheilosis

- Lesions of the nasal mucosa (including the nasal and oral lesions of erythema multiforme and lichen planus)
- Infant teething.

4.2 Posology and method of administration

Posology

Adults and children older than 2 years

Apply approximately 1 cm of the gel on to the sore area three to four times daily before meals and at bedtime.

Infants and children up to 2 years

Apply approximately 0,5 cm of the gel on to the sore area three to four times daily before meals and at bedtime.

Mode of administration

For local use. By topical application to the oral or nasal mucosa.

Instructions to open tube

1. Remove the cap and invert.
2. Place the cap over neck of tube.
3. Press firmly until seal is broken.

The gel should be applied on the painful or affected area with a well washed, clean finger or fingerstall and gently rubbed in.

4.3 Contraindications

Hypersensitivity to the choline salicylate, other non-acetylated salicylates or to any of the excipients listed in section 6.1. Active peptic ulceration.

For safety reasons, Teejel must not be used in the last trimester of pregnancy.

4.4 Special warnings and precautions for use

A maximum total daily dose of 250 mg choline salicylate (approximately ¼ of a tube) must not be exceeded. This corresponds to a maximum daily dose of approximately 1170 mg ethanol. Maximum application frequency of Teejel must not exceed 8 - 10 times per day. The quantity of gel per single application must not be greater than the size of a pea. The systemically available quantity of salicylate after application of Teejel to the oral mucosa is so minimal that the use of Teejel as recommended is also possible for children under 12 years of age with teething discomfort without prescription by a doctor.

There is a possible association between salicylates and Reye's Syndrome when given to children. Reye's Syndrome is a very rare disease, which affects the brain and liver and can be fatal. While the cause of Reye's Syndrome is unknown, some studies suggest a possible association between the development of Reye's Syndrome and the use of medicines containing acetylated salicylates or aspirin. Choline salicylate is a non-acetylated salicylate and the evidence for a causal association between choline salicylate and Reye's Syndrome is very limited.

Teejel contains alcohol (ethanol) and should not be used by persons with a history of alcohol abuse.

4.5 Interaction with other medicinal products and other forms of interaction

Salicylates, including choline salicylate, as contained in Teejel, may increase the effects of anticoagulants.

4.6 Fertility, pregnancy and lactation

Salicylates cross the placental barrier and pass into breast milk in minimal amounts. For reasons of safety, Teejel must not be used during the third trimester of pregnancy.

During the first two trimesters of pregnancy and during lactation the dosage indicated should not be exceeded.

4.7 Effect on ability to drive or use machines

Teejel has no or only negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Classification of undesirable effects has been based on the following frequencies:

Very common (≥ 1/10)

Common (≥ 1/100, < 1/10)

Uncommon (≥ 1/1 000, < 1/100)

Rare (≥ 1/10 000, < 1/1 000)

Very rare (< 1/10 000)

Not known (cannot be estimated from the available data)

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

b. Tabulated list of adverse reactions

System Organ Class	Adverse Event	Frequency
Blood and lymphatic system disorders	When used at very high doses, systemic effects of salicylate, especially on coagulation, cannot be ruled out.	Very rare
Gastrointestinal disorders	When used at very high doses, systemic effects of salicylate, especially on the gastrointestinal tract, cannot be ruled out.	Very rare
Skin and subcutaneous tissue disorders	Burning sensation on mucous membrane.	Not known
Nervous system disorder	Reye's syndrome	Very rare (see section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 OVERDOSE

After topical application no toxic side effects are to be expected. Salicylate intoxication, known as salicylism, may occur with large systemic doses or prolonged treatment duration. (see recommendations for maximum dosage in section 4.4).

Symptoms of overdose

Symptoms of salicylate overdose include headache, dizziness, tinnitus, hearing disturbance, confusion, somnolence, sweating, nausea and vomiting, diarrhea, fever and hyperventilation. Severe intoxication may be associated with central nervous system disturbances, delirium, tremor, disturbances of electrolyte balance, respiratory alkalosis, respiratory and metabolic acidosis, hyperthermia, dehydration, toxic circulatory and renal failure, cerebral and pulmonary oedema as well as coma.

Treatment of overdose:

Patients should be given supportive therapy or treatment for salicylate poisoning as necessary. Primary elimination (activated charcoal), monitoring of electrolyte balance, electrolyte compensation, glucose correction, IC support (ventilation, fluid supply), acceleration of elimination (alkalised, forced diuresis, hemodialysis), administration of diazepam in the event of cramping.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: A01AD11

A 34. Local analgesics

Pharmacotherapeutic group: Analgesics and antipyretics, salicylic acid and derivatives.

Upon local application of Teejel, the active substance choline salicylate provides good analgesic and anti-inflammatory action within an extremely short time. Pain relief is achieved after 2 to 3 minutes and maintained for about 2 to 3 hours. Teejel contains no sugar and shows good mucosal tolerability.

5.2 Pharmacokinetic properties

Choline salicylate is rapidly absorbed by the oral mucosa. Following local application of Teejel on the buccal mucosa, presence of salicylate in the blood could be demonstrated after 15 to 30 minutes. Choline salicylate is metabolised to the active primary metabolite salicylate. At higher concentrations of salicylate in serum conjugation of glycines is rapidly saturated. Therefore, slower glucuronide conjugation will be the limiting factor for salicylate elimination. In addition, salicylates eliminated via the bile may be re-absorbed as glucuronide conjugates. These factors will prolong the half-life of salicylate and explain why the increase of salicylate in plasma is non-linear with increasing salicylate doses. Salicylate is primarily eliminated by metabolisation in the liver. Excretion of the glycine and glucuronide conjugate metabolites is primarily by renal route. Factors reducing glomerular filtration or proximal tubular elimination will increase the serum concentration of salicylate.

5.3 Preclinical safety data

No tissue damaging effects were observed upon topical application of choline salicylate. Acute toxicity was studied in newborn rats; the LDL_{50} was between 7,0 and 7,4 g/kg body weight after 1 to 2 weeks.

Chronic toxicity was studied at doses of 200 to 1200 mg in dogs. No relevant results could be obtained either at the application site or for systemic substance-specific toxicity. Long-term animal studies for exclusion of a cancerogenic potential of choline salicylate has not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1 g Teejel gel contains: hydroxypropylmethyl cellulose, 382,0 mg ethanol 96 % *(m/m)*, purified water.

Glycerol, oil of anise, sodium cyclamate and menthol are added as flavourants.

6.2 Incompatibilities

Iron (III) salts, acidic substances.

6.3 Shelf life

3 years.

Teejel can be used for 12 months after opening the tube.

6.4 Special precautions for storage

Store at or below 25 °C.

Teejel does not require any special storage instructions.

6.5 Nature and contents of container

Teejel is packed into an aluminium tube having an epoxy/phenol resin inner coating. The tube is sealed with an aluminium film (needs to be pierced prior to first use) and has a white HPDE thread and screw cap.

Each tube contains 10 g of gel and is packed into a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

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Bedfordview

South Africa

Tel. 011 087 0000

8. REGISTRATION NUMBER(S)

50/4/0279

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2 October 1979

10. DATE OF REVISION OF TEXT

12 March 2025

Export details:

Namibia: NS0

Registration No. 14/13.1/0419

Botswana: S3

Reference No. B9311315

Zimbabwe: P

Registration No. Awaiting

Zambia: General Sale

Registration No. Awaiting